

REMARKS

1. Primers or probes of particular length are taught on page 11, first and second full paragraphs, on page 32, fourth full paragraph and in Table 3 of the instant specification. Hence, no issue of new matter arises and entry of the amendments is requested respectfully.

2. Claims 1-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 were rejected under 35 U.S.C. §§ 101 and 112, first paragraph. The Examiner believed the claims are not supported by a specific and substantial asserted utility or a well established utility and thus, also are not enabled. In the Advisory Action, the Examiner stated that while there is a link between the gene of interest and a particular disease, there was alleged to be a gap between stating that a marker is linked to a gene as compared to a marker being the particular morbid gene of a particular disorder.

The two rejections are traversed for the following reasons.

In the art of gene mapping and the practical use of discernable markers for genetic diagnosis of a disease, trait or other phenotype feature, any distinguishable marker that statistically or physically is found to be linked to a disorder, trait or other phenotype feature, can be used in a diagnostic assay to discern the presence or not of the disorder, trait or other phenotype feature. It is not necessary that the marker be the particular controlling gene of that disorder, trait or other phenotype feature. The closer the marker is to the controlling gene, the less likelihood of crossing over between the marker and the controlling gene, and the more predictable the marker will be for the presence or not of the controlling gene. Linkage analysis is a foundational feature of classical Mendelian genetics and serves as the basis for diagnostic assays to track a controlling gene, for example, when a polymorphism of the particular controlling gene is not available. A suitable marker is beneficial to track a trait, disease or other phenotype feature if the controlling gene has yet to be identified. Moreover, the chromosomal location of the trait, disease or other phenotype feature need not be known so long as the coexpression or simultaneous presence of the marker and of the trait, disease or other phenotype feature is established. The advent of DNA sequencing has provided numerous molecular

markers which has facilitated the use of nucleic acid polymorphisms as tags of a controlling gene in diagnostic assays.

The instant application relates to the discovery of a particular gene that maps to the chromosomal region previously found to be syntenic with various diseases, including ichthyosis. Because the gene is mapped to the same chromosomal region where those disorders are mapped, on its face, that leads to the conclusion that the gene is a marker for those disorders. The instant application describes polymorphisms of the ABCA12 gene that enables the artisan to identify different forms of the gene. That teaching makes clear there are discernable markers for ABCA12, and those markers can be used for ascertaining the presence of a disorder mapping to that same region or which is found, for example, to be linked to a polymorphism of ABCA12.

Attached hereto is the executed Declaration of Dr. Nicholas Duverger. As one of ordinary skill in the art, Dr. Duverger, on reading the application, concluded that based on the teachings of the specification, the instant inventors were in possession of a diagnostic assay for diseases that map to the same chromosomal region where the ABCA12 gene resides. Thus, the instant specification conveyed to one of skill in the art that the inventors described and were in possession of a diagnostic assay for diseases, such as ichthyosis, mapped to the particular chromosomal region where the ABCA12 gene was localized.

Clearly, the instant application, and hence the claims, provide a number of specific, substantial and credible uses of the nucleic acids of interest. The specification teaches thoroughly how to make and how to use a nucleic acid of interest. For example, probes identifying a mutation can be designed and used in a diagnostic assay for ichthyosis, as taught in the instant application. Therefore, utility exists and a prima facie case of non-enablement has not been made. Accordingly, withdrawal of the § 101 and § 112, first paragraph rejections is requested respectfully.

3. On page 6 of the Office Action, claims 2-5, 41-43, 47 and 51 were rejected under 35 U.S.C. § 112, first paragraph for an alleged want of written description. The Examiner maintained that the specification does not describe how to modify the nucleic acid of interest.

The rejection is traversed for the following reasons.

The claimed invention relates to nucleic acids encoding polypeptides with ABCA12 function, as clearly stated in the instant application, and some of those properties are recited in the claims.

Also, the specification teaches the association of ABCA12 with certain linked markers. Thus, any one fragment can be mapped to determine whether that nucleic acid retains the property of mapping to the chromosomal region where the genomic copy of the gene resides. Also, the instant specification teaches association of the ABCA12 gene expression with markers of skin and epithelium. Thus, the artisan can determine whether a fragment retains the association with the particular tissue expression of ABCA12.

Thus, the instant specification provides the sequences of ABCA12, characterizes the gene, the transcripts and polymorphisms thereof, and describes uses of the subject matter of interest. Hence, the written description requirement being satisfied, withdrawal of the rejection is in order.

4. On page 7 of the Office Action, claims 2, 5, 7, 9, 13, 16, 17, 47 and 51-63 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The issue relates to new matter, and more specifically of the possible need to recite probes of particular size that are not explicitly recited in the specification.

The rejection is traversed for the following reasons.

The nucleic acids relate to expressing an ABCA12 function or identifying a nucleic acid expressing an ABCA12 function. The nucleic acids also are related to markers for particular disease and other markers that map to the same chromosomal region and have the same tissue distribution.

The specification teaches nucleotides of interest of at least 1000 bp in length, for example, or 50 bp or fewer, for example, 40 bp or fewer, 35 bp or fewer, 25 bp or fewer, and 20 bp or fewer bp, see page 11, third full paragraph. That paragraph teaches nucleotides comprising 1500 bp as well.

Further examples are provided in paragraph 1 hereinabove. Also, the instant specification teaches a variety of polypeptides.

Thus, the specification clearly teaches a number of nucleic acids that comply with and are described by the language found objectionable. It is well settled that there need not be ipsissimis verbis concordance between the language in the specification and in the claims. All that is required is that the specification reasonably convey to the artisan what is being claimed, and the instant specification, in light of the state of the art of making and using probes, clearly teaches an extensive range of usable polynucleotides.

Nevertheless, for the purpose of compact prosecution, the claims were amended to recite probes of particular size explicitly recited in the specification. Clearly, an artisan would well recognize that once a probe or primer of particular size is obtained, one or more bases can be added to or removed from the probe or primer without departing from the spirit of the claimed invention. An artisan would well be able to practice the methods taught in the instant application and as known in the art to ascertain whether any variant of a probe or primer of particular claimed length having one or more bases added to or removed from retains the desired function and properties of interest.

The rejection now can be withdrawn.

5. Beginning at page 8 of the Office Action, the Examiner rejected claim 16 under 35 U.S.C. § 112, second paragraph.

Applicants thank the Examiner, his suggestion was adopted and hence, withdrawal of the rejection is requested respectfully.

6. On page 9 of the Office Action, the Examiner rejected claims 7, 13, 16 and 52-63 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the GenBank sequence of Ansorge et al.

The rejection is traversed for the following reasons.

The GenBank sequence of Ansorge et al. relates to a particular partial nucleic acid sequence. That GenBank sequence neither teaches nor suggests the claimed nucleic acids.

Thus, there is no anticipation and the rejection can be removed.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections, and early indication of allowance are requested respectfully. Should the Examiner believe that an interview would advance the prosecution of the instant application, Applicants invite her to contact the undersigned at the local exchange noted below.

The Commissioner is authorized to credit or debit Deposit Account No. 29180 if needed as relating to this paper to maintain pendency of the instant application. Finally, the undersigned avers having authority to act on behalf of applicants and the real parties in interest.

Respectfully submitted,

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